DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 13,2014

Insulet Corporation
Antonette M. DeLeo, MS, RAC
Senior Regulatory Affairs Specialist
600 Technology Park Drive, Suite 200
Billerica, MA 01821

Re: K140439
Trade/Device Name: OmniPod Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG, NBW
Dated: October 10, 2014
Received: October 14, 2014

Dear Ms. DeLeo,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140439

Device Name
OmniPod Insulin Management System

Indications for Use *(Describe)*

The OmniPod® Insulin Management System is intended for subcutaneous (below the skin) delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh capillary whole blood (in vitro) from the fingertip.

The glucose measurements should not be used for the diagnosis of or screening for diabetes or for neonatal use. The PDM glucose meter is intended for single-patient use and should not be shared.

OneTouch® Verio™ Test Strips are used with the built-in blood glucose meter with One Touch Verio technology for the quantitative measurement of blood glucose in fresh capillary whole blood drawn from the fingertips.

OneTouch Verio Control Solutions are used to check that the meter and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K140439

Submitter:	Insulet Corporation 600 Technology Park Drive Suite 200 Billerica, MA 01821 USA
Contact Person:	Antonette M. DeLeo, MS, RAC Senior Regulatory Affairs Specialist Telephone: 978-600-7443 Fax: 781-600-4329 E-mail: adeleo@insulet.com
Date Prepared:	November 7, 2014
Trade Name:	OmniPod Insulin Management System
Common Name:	Insulin Infusion Pump
Classification Name:	Pump, Infusion, Insulin
Product Code (Classification):	LZG
Product Code (Subsequent):	NBW
Product Code (Subsequent):	LFR
Predicate Device:	OmniPod Insulin Management System K122953
Device Description:	The OmniPod® Insulin Management System is a tubeless insulin pump intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh capillary whole blood (in vitro) from the fingertip. This System is comprised of two primary components, the insulin pump (Pod) and the remote controller (Personal Diabetes Manager). The Personal Diabetes Manager incorporates LifeScan OneTouch Verio blood glucose measurement capability through a built in blood glucose meter. The blood glucose meter uses One

	Touch Verio Test Strips. OneTouch Verio Level 3 (Mid) and OneTouch Verio Level 4 (High) Control Solutions are used to check that the meter and test strips are working together properly. OneTouch Verio Test Strips are included in the Starter Kit. OneTouch Verio Control Solutions are not included in the Starter Kit and must be purchased separately.
Statement of Intended Use:	The OmniPod Insulin Management System is intended for use in the management of insulin therapy and optional blood glucose monitoring by patients with diabetes mellitus.
Statement of Indications for Use:	The OmniPod® Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh capillary whole blood (in vitro) from the fingertip. The glucose measurements should not be used for the diagnosis of or screening for diabetes or for neonatal use. The PDM glucose meter is intended for single-patient use and should not be shared. OneTouch® Verio™ Test Strips are used with the built-in blood glucose meter with One Touch Verio technology for the quantitative measurement of blood glucose in fresh capillary whole blood drawn from the fingertips. OneTouch Verio Control Solutions are used to check that the meter and test strips are working together properly and that the test is performing correctly.
Summary of Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device.
Summary of Non-Clinical Data:	Insulet completed the appropriate validation and verification activities required by the *Guidance for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions Draft Guidance* and other guidance, as applicable. The following performance and safety testing has confirmed the proposed device to be substantially equivalent to the predicate device: • **Physical Characteristics:** the proposed device has been tested and successfully met physical dimension and weight requirements; • **Drop and Vibration:** the proposed device has been

tested and successfully met all of the relevant requirements for drop and vibration testing per IEC 60601-2-24;

- **Hardware:** the proposed device has been tested meets all of its associated hardware specifications;
- **Software:** documentation was prepared and submitted for a MAJOR level of concern device in accordance with FDA's Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices;*
- **Electrical Safety:** the proposed OmniPod Insulin Management System has been tested and successfully passed all of the relevant sections of IEC 60601-1 Medical electrical equipment, General requirements for Safety;
- **RF Wireless Safety and Performance:** the proposed device has been tested and verified to ensure proper wireless communication between the Pod and PDM;
- **Electromagnetic Interference:** the proposed device has been tested and successfully met all of the relevant sections (Radiated emissions, Electrostatic discharge immunity test, radiated radio frequency, electromagnetic field immunity, and Power frequency magnetic field immunity test) to satisfy compliance;
- **Alarm Sound Level:** the proposed device has been tested and successfully met requirements for sound pressure level;
- **Environmental:** the proposed device has been tested and successfully met IEC 60601-2-24 requirements for temperature, humidity and atmospheric pressure;
- **Battery Life:** the proposed device has been tested and successfully met the requirement of sufficient battery power for expected use;
- **Shipping:** the proposed device has been tested and successfully met requirements for aesthetic and functional integrity after shipping.

LifeScan completed appropriate testing to verify the product design and the laboratory/non-clinical blood glucose meter performance accuracy. The following evaluations were performed and have confirmed the proposed device to be substantially equivalent to the predicate device:

- Repeatability Precision
- Intermediate Precision
- Method Comparison (System Accuracy Capillary Sample)
- Device Comparison (Accuracy Equivalence)
- Linearity
- Effect of Temperature and Relative Humidity
  Operating temperature: 50°F to 104°F (10°C to 40°C)
  Operating relative humidity range: 20% to 90%
- Hematocrit
- Sample Identification
- Sample Volume
- Interferences: Exogenous and Endogenous
- Altitude
- Pre and Post Cleaning and Disinfection (System Accuracy)

Summary of Clinical Data:

LifeScan completed a clinical study, *Clinical Evaluation – Lay User and HCP Comparison to a Validated Method, Instructions for Use and System Use Evaluation*, to fulfill the requirements of ISO 15197:2003 (E) – Section 8 User Performance Evaluation. This evaluation confirmed the proposed device to be substantially equivalent to the predicate device:

Conclusion from Data:

Insulet believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indication for use. Performance, verification and validation testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria was met. Results of this testing have documented that the proposed device is substantially equivalent to the predicate device and is suitable for the labeled indication for use. Therefore, the proposed OmniPod Insulin Management System is substantially equivalent to the identified predicate.

Insulet Corporation has demonstrated that the proposed OmniPod Insulin Management System is substantially equivalent to the predicate device based upon indications for use, design, test results and the same fundamental scientific technology.